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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,400	09/12/2003	J. Christopher Marmo	D-4108	6665

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EXAMINER	
PREBILIC, PAUL B	
ART UNIT	PAPER NUMBER
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,400	MARMO ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *90,99,187,189,204,205 and 207* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 81-86,89-108,112,113,121-130,132,134-137,140,150,160-171,173,177-180,182-198 and 200-221.

Continuation of Disposition of Claims: Claims rejected are 81-86,89,91-98,100-108,112,113,121-130,132,134-137,140,150,160-171,173,177-180,182-186,188,190-198,200-203,206 and 208-221.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 17, 2007 has been entered.

Election/Restrictions

Applicant's election with traverse of Group III in the reply filed on November 16, 2005 is acknowledged. Also acknowledged is the August 14, 2006 election of (1) collagen other than collagen Type I (claims 190 and 208), (2) recombinant collagen (claim 203), (3) extracellular matrix proteins (claims 184 and 210) and (4) epithelium lifted with vacuum (claims 98 and 164) with traverse.

Claims 90, 99, 187, 189, 204, 205, and 207 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 90, 187 and 205 were also withdrawn because they required searching and examination of the non-elected species. Applicant timely traversed the restriction (election) requirement in the reply filed on August 14, 2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 81-85, 89, 91, 92, 94-95, 97, 105, 106, 108, 182-183, 185, 188, and 191 are rejected under 35 U.S.C. 103(a) as obvious over Peyman (US 5,964,748) in view of Gibson et al (US 5,171,318) or Kern (US 4,676,790). Peyman meets the claim language where the step of inserting the a lens is met by the step of inserting the solid curved material of a different refractive index because such a material is a lens; see Figure 19-27 and 32-40, column 12, line 26 to column 13, line 14 and column 14, line 39 to column 16, line 62. The vision correction device as claimed is made of the ocular material of Peyman (428,430), and the incision as claimed is the incision (418) of Peyman. Peyman teaches either implantation into either an "intrastromal or internal pocket (126)"; see column 12, lines 40-44. Peyman also teaches forming this pocket without rupturing Bowman's membrane; see column 12, lines 49-55. Since Bowman's membrane is not to be ruptured, this suggests that the pocket is formed anterior to Bowman's membrane and between at least some of the epithelial layer and Bowman's membrane because the epithelial layer is the only layer anterior to Bowman's membrane.

Alternatively, one could interpret Peyman as the Applicants have as inserting the lens in the stromal layer. However, the Examiner asserts that inserting the lens anterior to Bowman's membrane would have been obvious to an ordinary artisan because of Peyman's suggestion of not rupturing Bowman's membrane. Furthermore, there is no

criticality shown by the Applicants in the Applicants disclose indiscriminately forming the pocket in either the stromal layer of anterior to Bowman's membrane; see page 39, lines 16-26 of the present specification.

However, Peyman fails to disclose the use of an adhesive to secure the lens in the pocket as claimed. Gibson (see column 10, lines 17-44) and Kern (see column 4, lines 25-48) both teach that it was known to secure similar devices within Bowman's membrane with adhesive. Therefore, it is the Examiner's position that it would have been obvious to do the same in the Peyman method in order to more securely hold the Peyman device to Bowman's membrane as taught by Gibson or Kern.

With regard to claim 84, Applicants are directed to Figures 46-53 and column 18, line 15 et seq.

With regard to claim 85, it was inadvertently left out of the rejection statement of the previous Office action. However, it should have been included with the first prior art rejection supra. Clearly, the lens is inherently deformed as it is formed particularly when the material is in a semisolid state such deformation would inherently occur due to gravity acting on the device while laying on a solid surface.

With regard to claim 183, the curved surface of the ocular material is the cellular attachment element to the extent required by the claim language.

Claims 96, 100-102, 150, 178, 179 and 184 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,964,748), Gibson, and Kern, as applied to claims 81-84, 89, 91, 92, 94-95, 97, 105, 106, 108, 183, 185, 188, and 191 above, and further in view of Brown et al (US 4,959,353). Peyman fails to disclose the application

of a healing agent as claimed. However, Brown teaches that it was known to apply a healing agent to the corneal tissue after similar surgical operations; see the title and column 1, lines 15-35. Therefore, it is the Examiner's position that it would have been obvious to apply a healing agent to the cornea in the Peyman method in order to promote healing therein.

With regard to claim 100, Applicants are directed to column 4, lines 43-57 of Brown.

Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,964,748), Gibson, and Kern, as applied to claims 81-84, 89, 91, 92, 94-95, 97, 105, 106, 108, 183, 185, 188, and 191 above, and further in view of Perez (US 6,880,558). Peyman fails to disclose the use of a vacuum to lift up a corneal flap or corneal tissue. However, Perez teaches that it was known to do the same in similar procedures; see Figure 5 and column 10, lines 35-58. Therefore, it is the Examiner's position that it would have been obvious to lift the flap or tissue in the Peyman procedure with a vacuum as taught by Perez for the same reasons that Perez does the same and in order to reduce trauma to the corneal tissue as compared to other tissue moving procedures in the art.

Claims 121-123, 126, 132, 140, 160, 163, 165, 166, 173, and 192 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,964,748), Gibson, and Kern, as applied to claims 81-84, 89, 91, 92, 94-95, 97, 105, 106, 108, 183, 185, 188, and 191 above, and further in view of Miller (US 6,335,006). Peyman fails to disclose the use of a liquid to loosen the epithelial layer as claimed. However, Miller

teaches that it was known to use liquids of various types to loosen epithelial layers; see column 1, line 65 to column 3, line 29. Therefore, it is the Examiner's position that it would have been obvious to use the Miller procedure to loosen the epithelial tissue in Peyman's process for the same reasons that Miller does the same and in order to promote a clean separation of the tissue layers.

Claims 112, 113, 124, 125, 134-137, 161, and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, Gibson, Kern, and Miller as applied to claims 121-123, 126, 132, 140, 160, 163, 165, 166, 173, and 192 above, and further in view of Perez (US 2003/0220653). Peyman fails to teach the use of a hypertonic solution to loosen the epithelial layer. However, Perez teaches that such solutions were known to the art at the time the invention was made; see paragraph [0150]. Therefore, it is the Examiner's position that it would have been obvious to utilize a hypertonic solution for the loosening procedure of Miller for the same reasons that Perez utilizes the same and in order to prevent the use of toxic residues to the eye tissue that could cause toxicity problems after surgery.

The hypertonic solution subject matter of Perez has an effective filing date of January 17, 2002 based upon provisional application 60/350,003; see paragraphs [0050] to [0052] thereof and see MPEP 2163.03 III that is incorporated herein by reference.

With regard to claims 134-137, Applicants are directed to see paragraphs [0094] to [0105] of Perez.

Claim 164 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, Gibson, Kern, and Miller as applied to claims 121-123, 126, 132, 140, 160, 163, 165, 166, 173, and 192 above, and further in view of Perez (US 6,880,558). Peyman fails to disclose the use of a vacuum lift corneal tissue during corneal procedures. However, However, Perez teaches that it was known to do the same in similar procedures; see Figure 5 and column 10, lines 35-58. Therefore, it is the Examiner's position that it would have been obvious to lift the flap or tissue in the Peyman procedure with a vacuum as taught by Perez for the same reasons that Perez does the same and in order to reduce trauma to the corneal tissue as compared to other tissue moving procedures in the art.

Claim 171 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, Gibson, Kern, and Miller as applied to claims 121-123, 126, 132, 140, 160, 163, 165, 166, 173, and 192 above, and further in view of Peyman (US 2004/0015234). Peyman ('748) discloses utilizing various instruments to make incisions in the cornea, but fails to teach that use of a microkeratome. However, Peyman ('234) teaches that it was known to utilize a microkeratome to make incisions in similar corneal procedures in the art. Therefore, it is the Examiner's position that it would have been obvious to utilize a microkeratome to make the incisions of Peyman ('748) for the same reasons that Peyman ('234) utilizes the same and in order to make a very clean and precise incision as compared to other procedures of the art.

Claim 177 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, Gibson, Kern, and Miller as applied to claims 121-123, 126, 132, 140, 160,

163, 165, 166, 173, and 192 above, and further in view of Brown (US 4,959,353). Peyman fails to disclose the application of a healing agent as claimed. However, Brown teaches that it was known to apply a healing agent to the corneal tissue after similar surgical operations; see the title and column 1, lines 15-35. Therefore, it is the Examiner's position that it would have been obvious to apply a healing agent to the cornea in the Peyman method in order to promote healing therein.

Claims 180, 192-196, 200-202, 206, and 209 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,964,748), Gibson, and Kern, as applied to claims 81-84, 89, 91, 92, 94-95, 97, 105, 106, 108, 183, 185, 188, and 191 above, and further in view of Cumming (US 5,984,914). Peyman fails to disclose the use of cooling as claimed. However, Cumming teaches that is was known to cool ablated tissue when forming a pocket to prevent further damage due to heat; see claims 1 and 8 as well as column 3, lines 58-63. Therefore, it is the Examiner's position that it would have been obvious to cool the eye tissue during pocket formation for the same reasons that Cumming did the same.

Claim 211 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, Gibson, Kern, and Cumming as applied to claim 194 above, and further in view of Nigam (US 6,361,560). Peyman fails to disclose the use of a microkeratome to form the pocket as claimed. However, Nigam teaches that it was known from pockets with microkeratome within the art; see column 1, lines 40-44 and column 3, lines 26-32. For this reason, it is the Examiner's position that it would have been obvious to form the

pockets of Peyman with a microkeratome for the same reasons that Nigam does the same and because such devices are widely available to an ordinary artisan.

Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, Gibson, and Kern as applied to claim 81 above, and further in view of Peyman (US 2004/0015234). Peyman ('748) discloses utilizing various instruments to make incisions in the cornea, but fails to teach that use of a microkeratome. However, Peyman ('234) teaches that it was known to utilize a microkeratome to make incisions in similar corneal procedures in the art. Therefore, it is the Examiner's position that it would have been obvious to utilize a microkeratome to make the incisions of Peyman ('748) for the same reasons that Peyman ('234) utilizes the same and in order to make a very clean and precise incision as compared to other procedures of the art.

Claims 197 and 198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, Gibson, Kern, and Cumming as applied to claim 194 above, and further in view of Perez (US 2003/0220653). Peyman fails to teach the use of a salt and water solutions to the cornea. However, Perez teaches that such solutions were known to the art at the time the invention was made; see paragraph [0150]. Therefore, it is the Examiner's position that it would have been obvious to utilize a hypertonic solution for the loosening procedure of Peyman for the same reasons that Perez utilizes the same and in order to prevent the use of toxic residues to the eye tissue that could cause toxicity problems after surgery.

Claims 186 and 190 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, Gibson, and Kern as applied to claim 81 above, further in view of Isseroff

et al (US 2002/0039788). Peyman discloses making lenses out of collagen but not out of recombinant collagen as now claimed. However, Isseroff teaches that it was known to make similar corneal repair materials out of recombinant collagen. For this reason, it is the Examiner's position that it would have been obvious to utilize recombinant collagen as the collagen of Peyman for the same reasons that Isseroff uses the same or for improved healing properties.

Claims 203 and 208 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, Gibson, Kern, and Cumming as applied to claim 194 above, and further in view of Isseroff et al (US 2002/0039788). Peyman discloses making lenses out of collagen but not out of recombinant collagen or collagen other than Type I as now claimed. However, Isseroff teaches that it was known to make similar corneal repair materials out of recombinant collagen or collagen other than Type I. For this reason, it is the Examiner's position that it would have been obvious to utilize recombinant collagen as the collagen of Peyman for the same reasons that Isseroff uses the same or for improved healing properties.

Claim 210 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, Gibson, Kern, and Cumming as applied to claim 194 above, and further in view of Brown (US 4,959,353). Peyman fails to disclose the use of growth factors such as healing agents as claimed. However, Brown teaches that it was known to apply a healing agent to the corneal tissue after similar surgical operations; see the title and column 1, lines 15-35. Therefore, it is the Examiner's position that it would have been

obvious to apply a healing agent to the cornea in the Peyman method in order to promote healing therein.

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,964,748), Gibson, and Kern, as applied to claims 81-85, 89, 91, 92, 94-95, 97, 105, 106, 108, 183, 185, 188, and 191 above, and further in view of Civerchia (US 4,983,181). Peyman fails to disclose the step of removing an old lens and replacing it with a new one as claimed. However, Civerchia teaches that it was known to the art to remove and replace lenses as necessary; see column 7, lines 7-20. Therefore, it is the Examiner's position that it would have been obvious to do the same in the Peyman method for the same reasons that Civerchia does the same.

Claims 103 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman (US 5,964,748), Gibson, and Kern, as applied to claims 81-85, 89, 91, 92, 94-95, 97, 105, 106, 108, 183, 185, 188, and 191 above, and further in view of Viegas et al (US 5,587,175). Peyman fails to disclose the application of a cellulosic agent to the eye as claimed. However, Viegas teaches that it was known to the art to apply cellulosics during eye surgery as a way to treat and fill the same; see the abstract and column 5, lines 53-59. Therefore, it is the Examiner's position that it would have been obvious to apply cellulosics to the eye during the Peyman method for the same reasons that Viegas does the same.

Claims 127-130, 167-170, and 214-221 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, Gibson, Kern, and Miller as applied to claims 121-123, 126, 132, 140, 160, 163, 165, 166, 173, and 192 above, and further in view of

Viegas et al (US 5,587,175). Peyman fails to disclose the application of a cellulosic agent to the eye as claimed. However, Viegas teaches that it was known to the art to apply cellulosics during eye surgery as a way to treat and fill the same; see the abstract and column 5, lines 53-59. Therefore, it is the Examiner's position that it would have been obvious to apply cellulosics to the eye during the Peyman method for the same reasons that Viegas does the same.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

With regard to the arguments that the Peyman rejection is not tenable, the Examiner has modified the rejection to explain how the claimed invention is at least obvious in view thereof.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Prebilic
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Art Unit 3738